

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT OF TEXAS

JUL - 1 2014

DAVID J. MALAND, CLERK
BY
DEPUTY _____

UNITED STATES OF AMERICA)

Ex rel. Karen E. Malcolm,)
Plaintiff,)

V.)

ELITE LAB SERVICES, LLC,)
GERARD C. DENGLER,)
SUZANNE DENGLER,)
ALLAN JOHNSTON,)
Defendants.)

Civil Action No. 4:14cv437
Judge: Bush

FILED IN CAMERA
AND UNDER SEAL

FALSE CLAIMS ACT
MEDICARE FRAUD

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT PURSUANT TO
TITLE 31, U.S.C., SECTIONS 3729-3732 OF THE
FEDERAL FALSE CLAIMS ACT

The United States of America, by and through *qui tam* relator Karen E. Malcolm (Relator) brings this action under Title 31, United States Code, section 3729, *et seq.*, as amended (The False Claims Act) to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States of America.

INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America for violations of the False Claims Act arising from:

a) false and fraudulent claims knowingly presented, and caused to be presented, to the United States through the Medicare system for payment and approval in violation of Title 31 U.S.C. Section 3729(a)(1)(A);

b) false material records and statements knowingly made, used and caused to be made and used which were material to false and fraudulent claims submitted to the United States through the Medicare system in violation of Title 31 U.S.C. Section 3729(a)(1)(B);

c) Conspiring to knowingly present and cause to be presented false and fraudulent claims and to knowingly make, use and cause to be made or used false records and statements material to a false and fraudulent claim for payment and approval by the United States through the Medicare system, by the Defendants, their agents, employees and co-conspirators with respect to claims for payments of laboratory services provided as an authorized Medicare service provider in violation of Title 31 U.S.C. Section 3729(a)(1)(C).

2. Each incident of presenting and causing to be presented a false claim to the United States or making and causing to be made a false record or statement or conspiring to do the same is a separate violation of the False Claims Act. 37 U.S.C. section 3729(a)(1)(A), (B) and (C). For each violation the Defendants are liable for a civil penalty of up to \$11,000.00 and damages treble the amount of the loss to the government. 37 U.S.C. section 3729(a)(1).

3. The False Claims Act allows any person having information about a false or fraudulent claim against the government to bring an action on behalf of the government as a *qui tam* seeking civil penalties and damages. 31 U.S.C. section 3730(b)(1). The Act also sets forth detailed procedures regarding the Government's ability to intervene in the lawsuit. 31 U.S.C. 3730(b) and (c). The Act also requires that this complaint be filed under seal and remain so sealed for sixty days. 31 U.S.C. section 3730(B)(2).

THE PARTIES

4. Relator, Karen E. Malcolm, is an individual and a resident of Smith County. She is an employee of Elite Lab Services, LLC. She has been so employed for approximately three years

and currently serves as billing supervisor. Relator has standing to bring this lawsuit on behalf of the government pursuant to Title 31 U.S.C. section 3703(b)(1).

5. As a part of her duties as billing supervisor, Relator in the normal course of her work is familiar with claims submitted to Medicare and third party providers for services rendered by Elite Lab Services. These claims include requests for reimbursement for mileage driven in the collection of samples for analysis.

6. Following an audit in November and December, 2013, Relator, for the first time, discovered that the actual mileage driven to collect samples and return them to Elite Lab Services was significantly less than what was being submitted in claims to the Medicare system. In accordance with the Elite Lab Services Employee Handbook, Relator confronted Defendants with the discrepancy. Defendants denied any wrong doing. Relator immediately sought counsel.

7. Defendant Elite Lab Services, LLC, is a domestic company with its principle place of business in Tyler, Smith County, Texas. It is licensed under the Clinical Laboratory Improvement Amendments (CLIA) to engage in collecting and analyzing biological specimens for medical and screening purposes. Elite Lab Services does business throughout east Texas, southern Arkansas and eastern Oklahoma. Elite Lab Services, LLC, is an authorized Medicare Service provider which submits an average of five hundred claims for clinical laboratory and related services per day. The primary customers of Elite Lab Services, Inc., are nursing homes and facilities that offer inpatient care, but do not have an in-house laboratory.

8. Defendant Gerard C. Dengler is an individual and a resident of Smith County, Texas. He is the sole owner of Elite Lab Services, LLC. Gerard C. Dengler is engaged in the day to day administrative operations of Elite Lab Services and makes decisions regarding the submission of claims to Medicare for mileage driven by phlebotomists and couriers.

9. Defendant Suzanne Dengler is an individual married to Defendant Gerard C. Dengler and is a resident of Smith County, Texas. She serves as Chief Operating Officer of Elite Lab Services, LLC. Suzanne Dengler has thirty years' experience in the clinical laboratory field and meets the educational requirements necessary for approval under CLIA. Suzanne Dengler likewise makes decisions regarding the submission of claims to Medicare for mileage driven by phlebotomists and couriers. She is aware of and approves all contracts with skilled nursing facilities.

10. Defendant Allan Johnston is an individual and a resident of Smith County, Texas. He serves as vice president of operations for Elite Lab Services. Allan Johnston oversees the day to day operations of the lab. He is responsible for decisions regarding services rendered and determining how reimbursement for mileage is attributed to services rendered.

JURISDICTION AND VENUE

11. This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. section 1331, and 31 U.S.C. section 3730. There have been no public disclosures of the allegations contained herein which would bar jurisdiction under 31 U.S.C. section 3730(e).

12. This court has jurisdiction over the parties to this action by virtue of their status as business entities or individuals existing in, residing in and doing business in the United States.

13. Venue is proper in the Eastern District of Texas because all parties can be found in, reside in or transact business in the Eastern District of Texas.

14. As required under 31 U.S.C. section 3730(b)(2), Relator has contemporaneously with this filing served the United States, pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure with a copy of this complaint and written disclosure of substantially all material evidence and information supporting the claims herein which is now in the possession of Relator.

THE ELITE SCHEME TO DEFRAUD

The Medicare System.

15. The federal Medicare Program, established in 1965 by Title XVIII of the Social Security Act, consists of two parts: Medicare Part A, which authorizes the payment of federal funds for hospitalization and post hospitalization care; and Medicare Part B, which authorizes federal funding for medical and other health services not a part of hospitalization.¹ Payment by Medicare is not made to the individual receiving the medical care, but rather is made to the entity providing the treatment.

16. As provided in the Social Security Act, the Secretary of Health and Human Services administers the Medicare Program through Centers for Medicare and Medicaid Services (CMS). Medicare enters into provider agreements with health care providers and suppliers to establish the facilities' eligibility to participate in the Medicare Program. In order to be eligible for payment under the Medicare program, providers and suppliers must certify in the provider agreement that they understand payments of claims are conditioned on the claims and the underlying transactions complying with applicable laws, regulations and program instructions.

17. Acting between CMS and the authorized Medicare provider is Novitas Solutions, a government contractor who essentially serves the function of claims administrator. Claims for payment are submitted by providers or suppliers to Novitas, and claims are approved for payment or denied payment by Novitas. The provider agreement clearly defines third party intermediaries such as Novitas as agents of the government and specifies that claim submissions to intermediaries are claim submissions to the government.

¹ Medicare Part B, also provides funding in other limited instances, such as when a person exhausts all Part A funding, but those instances are not related to the issues presented by this complaint.

18. Since 1997, reimbursement to authorized Medicare service providers under the two different Medicare parts -- A and B -- have been structured very differently. Medicare Part B pays claims as a fee for service system. Medicare Part B allows a service provider to include a claim for reimbursement of mileage in certain circumstances. The Medicare Fee Schedule provides a maximum allowable fee per service provided. The provider electronically submits a claim to the intermediary, the intermediary makes a payment decision and, where appropriate, pays the claim.

19. In contrast, Medicare Part A pays authorized service providers on a per diem basis. Because Part A covers patients who are hospitalized or in skilled nursing recovery facilities, payment is made from Medicare to that facility on a flat per day rate. This flat rate covers the routine, ancillary and capital-related costs associated with the patient's stay. If the patient needs a service not offered in-house, such as lab analysis of a blood or urine specimen, it is the facility's responsibility to arrange and pay for the service.

Elite Mileage Claims

20. Elite Lab Services, Inc., (Elite) executed a Medicare Service Provider agreement and became an authorized Medicare service provider in 2005. Elite provides laboratory collection and analysis services directly under Part B and contracts with Part A skilled nursing facilities to provide collection and analysis of samples from Part A patients.

21. Elite employs phlebotomists to travel to the location of both the Part A and Part B patients for collection of blood samples and to transport the sample to the laboratory in Tyler, Texas, for analysis. Under Medicare regulations, Elite is permitted to submit a claim to the government for reasonable mileage driven to collect and transport the samples for analysis. The mileage guidelines specify that the number of miles driven per day in connection with collecting

samples for veni-punctures and transporting samples to the lab is to be apportioned between the number of veni-punctures performed in a day so that one veni-puncture does not bear a disproportionate expense. CMS Medicare claims processing regulations state, "At no time will the laboratory be allowed to bill for more miles than are reasonable, or for miles that are not actually traveled by the laboratory technician."

22. Elite uses two different software programs to process and bill for its services. CyberLAB is a laboratory information management system that interfaces with analysis instrumentation and the billing system. CyberLAB is designed to assist Elite in complying with Medicare's regulations regarding mileage reimbursement. Data regarding the phlebotomist's collection routes and route mileage must be manually programmed into the software. Then the program automatically apportions route mileage to each blood sample drawn for testing. Once the apportionment is calculated for a day of service, that information is transferred to the interfaced billing software, Telcorp.

23. Elite began using CyberLAB software in 2009. Elite's management team, Defendants Gerard C. Dengler, Suzanne Dengler and Allan Johnston, are the only people with the administrative access necessary to enter route and mileage data into the program.

24. However, these are not the routes which are actually driven by the Elite-employed phlebotomists. The mileage calculated by CyberLAB and uploaded to the Telcorp billing software is grossly exaggerated. Defendants Gerard C. Dengler, Suzanne Dengler and Allan Johnston knowingly and intentionally programmed CyberLAB to inflate the mileage calculations in the following manner and means, among others.

25. Route manipulation. Elite's phlebotomist's supervisor designs daily collection routes to efficiently cover its client institutions and to permit the phlebotomists to complete their work

within an eight hour shift. There are no more than thirty-six routine collection routes. But, instead of programming CyberLAB with the actual phlebotomist's routes, the individual Defendants programmed 61 different routes. Many of these routes are geographically convoluted and could not be driven in a single work shift. Often they contain towns in different states in order to maximize the mileage being charged.

26. Route Triggering. The individual Defendants have programmed CyberLAB in such a manner that if any one facility on a particular route has a blood sample requested to be drawn on a given day, the mileage for the whole route is included for the day whether the whole route was driven or not.

27. Route Updating. When an in-patient facility falls out of contract with Elite, the CyberLAB administrators sometimes fail to update the routes in CyberLAB, meaning the facility stays on the route and mileage is added as if a phlebotomist drove there each time another facility on that same route requisitions a blood draw. For example, in December, 2010, thirty-five facilities owned by the same corporation cancelled their contract with Elite. Nevertheless, for the next three years those thirty-five facilities remained on the pre-designated routes in CyberLAB, and each day any facility on a route shared with one of those homes requested a blood draw, the Medicare system was billed for a phlebotomist driving to the cancelled facility as well.

28. Exaggeration of Mileage. The mileage programmed by the individual Defendants for each route in CyberLAB do not accurately reflect the mileage necessary to drive to each facility on the route.

29. Route Origination and Termination. The individual Defendants programmed routes into CyberLAB as if the phlebotomist leaves from the home office in Tyler, Texas, daily, drives to

the assigned facilities, and then returns the samples to the laboratory in Tyler, Texas. However, many of the phlebotomists live near the outlying portions of Elite's service areas, such as Texarkana and Waco. These phlebotomists do not start the day at the lab in Tyler. They receive their assignments via email at home and then they drive from their home to the assigned facilities and return the sample to the local Elite Office where it is sent by courier to Tyler. The Defendants programmed CyberLAB so that each day there would be at least twelve routes that included a facility in Arkansas. Of the thirty-six phlebotomists that drive routes each day, NONE performs venipunctures in Arkansas and drives them back to Tyler. Twice a day couriers, who are not phlebotomists, pick up samples from the Texarkana office and bring them to Tyler. However, Medicare regulations do not allow a claim for courier mileage so the Elite routes are written as if each individual phlebotomist drives the samples back.

30. Random Addition of Miles. On a regular basis Defendants Suzanne Dengler and Alan Johnston manually add miles to the CyberLAB calculations for a given day. Records indicate that as many as four thousand miles are regularly added to the already exaggerated number of miles driven in a day. Additionally, Defendants Suzanne Dengler and Alan Johnston randomly manipulate the total number of venipunctures on a given day of service, at times as much as a twenty-five percent reduction, so that the number of miles per Medicare venipuncture is increased.

31. The Use of Reference Laboratories. When an unscheduled emergency blood test is ordered by a doctor to be performed stat, regulations require that the results be provided to the doctor within a six hour time frame. In order to accomplish this, the laboratory is allowed to use a subcontracting lab, called a reference lab, in order to complete the analysis timely. Elite frequently finds itself in the position to use reference laboratories, especially when there are stat

calls from outlying areas such as Arkansas and Waco. However in those instances where a phlebotomist who lives in Arkansas or Waco goes to a facility nearby to make a draw and then takes it to a local reference laboratory for analysis, Elite bills the government as if the phlebotomist left Tyler, Texas, drove to the facility for the venipuncture and then returned the sample to Tyler, Texas, for analysis.

32. Double Billing. Frequently when Elite has emergency requisitions for blood draws or requisitions which are added outside the daily route, Elite sends a phlebotomist directly to the facility to make those draws. If there is more than one patient needing a venipuncture the phlebotomist performs those in the same trip to the facility. When the claim is submitted to Medicare, however, it is submitted as if two separate trips were made to the facility, therefore double or tripling, as the case may be, the mileage actually driven.

33. These, and other intentional acts of the Defendants which exaggerate the mileage claimed to have been driven to collect specimens have resulted in a gross inflation of mileage billed to the Medicare system.

34. Defendants Gerard C. Dengler, Suzanne Dengler and Allan Johnston have actual knowledge that the CyberLAB routes are not the actual routes driven by the phlebotomists and that the mileage calculated by CyberLAB is grossly excessive. As the owner, Chief Operating Officer and Vice President of Operations they have actual knowledge that at the end of each pay period the phlebotomists and couriers submit the actual mileage driven in their private vehicles to their supervisor. They are reimbursed for these miles and a record of their mileage is maintained by the company.

35. Because of the intentional manipulation by the individual Defendants of the mileage calculations, each claim which included a mileage component submitted by Elite to Medicare, at

least since the implementation of the CyberLAB software, claimed reimbursement for more miles than was actually driven by technicians in violation of Medicare rules and regulations.

36. The individual Defendants, Gerard C. Dengler, Suzanne Dengler and Allan Johnston, acting individually and in their capacities as the owner and/or executive staff employees of Elite, knowingly presented, or caused to be presented each of the false claims referred to in the preceding paragraph.

37. The individual Defendants, Gerard C. Dengler, Suzanne Dengler and Allan Johnston, acting individually and in their capacities as the owner and/or executive staff employees of Elite, knowingly made or caused to be made a false record in support of each of the claims referred to in paragraph 35.

Elite Kickbacks and Inducements

38. When a proposed Medicare service provider, such as Elite, enters into a Medicare provider agreement with the government, the provider certifies to the government that the entity agrees to abide by applicable law in submitting claims for reimbursement. The Federal Anti-Kickback Law, Title 42 U.S.C. section 1320a-7b(b)(1)(A) and 2(A), is specifically mentioned as one of the applicable laws in the provider agreement. Payment of the claim is expressly made contingent on this certification in the Medicare regulations.

39. When a Medicare service provider induces a health care facility to contract with the service provider for all of the facility's Medicare Part B patients, and in exchange, the service provider agrees to provide service to the facility's Medicare Part A patients at a significantly reduced rate, the service provider is in violation of the Anti-Kickback Law. In essence the service provider who makes such an agreement is increasing the profit margin of the facility and therefore putting money in the hands of the ownership. Elite regularly engages in this practice.

40. Each individual Defendant has actual knowledge of this practice. Each contract Elite enters into with a client facility states the rate at which Elite will be paid for services it may render to the client's Part A patients. These contracts are signed by an agent of Elite and maintained on the company's premises.

41. Currently Elite services 151 facilities with both Part A and Part B patients. Of those 151 facilities, 121 have been illegally induced to exclusively allow Elite to service its Part B patients.

42. These impermissible rates render every Part B claim filed for service to a patient in an induced facility a falsely certified claim because the claim was acquired in violation of the Anti-Kickback Statute and in violation of Elite's provider's certificate.

LEGAL ALLEGATIONS

Conspiracy to Submit False Claims and Make False Records

43. Relator specifically alleges that beginning six years prior to the filing of this original complaint, and continuing up to and including the date of the filing of this original complaint, in Tyler, Texas, **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston**, did knowingly conspire, confederate and agree together to violate a law of the United States, to wit: Title 31, United States Code, section 3729 (a)(1)(A) and (B) prohibiting knowingly presenting or causing to be presented false and fraudulent claims for payment or approval, and prohibiting knowingly making using, or causing to be made or used false records or statements material to false or fraudulent claims, in violation of Title 31 U.S.C. section 3729(a)(1)(c) and that such act was the cause in fact of harm and damage to the United States of America.

44. In furtherance of the unlawful conspiracy and to fulfill the objective there of the **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan**

Johnston did act in the manner and means alleged in paragraphs 15 through 37 above which are re-urged and incorporated herein, and did commit the overt acts specifically listed in paragraphs 25 through 32 above which are re-urged and incorporated herein.

False Claims

45. Relator specifically alleges that on each of the dates specified in Attachments 1-4, which are incorporated herein, in Tyler, Texas, and as a part of the scheme alleged in Paragraphs 15 through 37, **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** did knowingly present and cause to be presented a false or fraudulent claim for payment or approval to the United States by submitting to the Federal Medicare System a claim for reimbursement of mileage driven in connection with phlebotomy and laboratory services when **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** knew that such claims were false because such mileage had not in fact been driven in connection with phlebotomy and laboratory services in violation of Title 31 U.S.C. section 3729 (a)(1)(a) and that such act was the cause in fact of harm and damage to the United States of America.

False Records

46. Relator specifically alleges that on each of the dates specified in Attachments 1-4, which are incorporated herein, in Tyler, Texas, and as a part of the scheme alleged in Paragraphs 15 through 37, **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** did knowingly make, use and cause to be made and used a false record or statement of mileage driven in connection with phlebotomy and laboratory services, which was material to a false and fraudulent claim, when **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** knew that such record or statement was false in

that the mileage contained in the record or statement had not in fact been driven in connection with phlebotomy and laboratory services in violation of Title 31 U.S.C. section 3729 (a)(1)(b) and that such act was the cause in fact of harm and damage to the United States of America.

False Certifications

47. Relator specifically alleges that on each of the dates specified in Attachments 5–8 which are incorporated herein, in Tyler, Texas, and as a part of the scheme alleged in paragraphs 15 through 37 above, **Defendants Elite Lab Services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** did knowingly present and cause to be presented a false or fraudulent claim for payment or approval to the United States by submitting to the Federal Medicare System a claim which had been unlawfully induced in violation of the Anti-Kickback statute when **Defendants Elite Lab services, Inc., Gerard C. Dengler, Suzanne Dengler and Allan Johnston** knew that such claims had been induced by offering contracts to Medicare Part A health care providers at rates below the Medicare fee schedule and below cost in exchange for the exclusive right to service and bill for Medicare Part B patients in violation of Title 31 U.S.C. section 3729 (a)(1)(a) and that such act was the cause in fact of harm and damage to the United States of America.

JURY DEMAND

48. Relator demands a trial by jury on these allegations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, United States of America, through Relator, requests the following relief:

A. That defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq.* or any other applicable law;

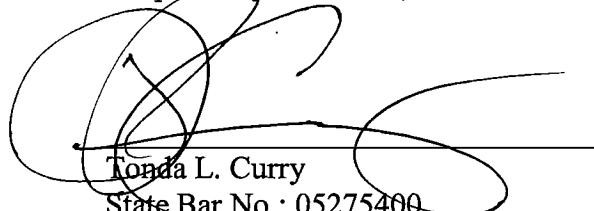
B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729, in addition to applicable pre-judgment and post judgment interest on the amount of the judgment;

C. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act.

D. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

E. That Relator receive such other relief as the Court deems just and proper.

Respectfully submitted,



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